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| 10/594,839 | 09/28/2006 | Motoaki Kamachi | Q80934 | 3708 |
| 23373 7590 09/04/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 | | | | |
| EXAMINER | | | | |
| GOON, SCARLETT Y | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/594,839

Applicant(s)

KAMACHI ET AL.

Examiner

SCARLETT GOON

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (FTO/SE/US)
Paper No(s)/Mail Date 28 September 2006
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

The preliminary amendment filed on 28 September 2006 in which claims 6 and 7 were currently amended, and claims 8-20 were newly added, is acknowledged.

Claims 1-20 are pending in the instant application.

Priority

This application is a National Stage entry of PCT/JP05/06411 filed on 25 March 2005 and claims priority to Japan foreign application 2004-105929 filed on 31 March 2004 and U.S. provisional application no. 60/560607 filed on 9 April 2004. A certified copy of the foreign priority document in Japanese has been received. No English translation has been received.

Information Disclosure Statement

The information disclosure statement (IDS) dated 28 September 2006 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609, unless otherwise indicated. Accordingly, it has been placed in the application file and the information therein has been considered as to the merits. The reference entitled "Arabinogalactan" was not considered because an English translation was not provided.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of a "derivative" in these claims renders the claims herein indefinite. The recitation of a "polysaccharide derivative" or "anhydrosaccharide derivative" is not clearly defined in the specification. Thus, the metes and bounds of the term "derivative" are unclear. The 10th edition of the Merriam-Webster's Collegiate Dictionary (Merriam-Webster Incorporated: Springfield, Massachusetts, 1993, pp 311) defines "derivative" as, "a chemical substance related structurally to another substance and theoretically derivable from it." Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "polysaccharide derivative" or "anhydrosaccharide derivative" herein. Thus, it is unclear and indefinite as to how the "derivative" herein is encompassed thereby.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Section [0001]

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP2003-252904 by Kakuchi *et al.* (IDS dated 28 September 2006, machine translation) in view of US Patent No. 6,197,319 B1 to Wang *et al.* (PTO-892, Ref. A).

Kakuchi *et al.* teach a method for manufacturing multi-branching polysaccharides which are obtained by polymerization in the presence of a cation or anion initiator and an anhydrosugar (p. 4, section 0003). The multi-branching polysaccharides are useful as a thickener in a biocompatible gel or a medically-based material (p. 3, section 0001). The anydrosugars can be a 1,6-anydrosugar, a 1,4-anhydrosugar, a 1,3-anhydrosugar, or a 1,2-anydrosugar (p. 4) The degree of branching of the multi-branching

polysaccharide is between 0.05 to 1.00 (p. 5, section 0005). The water-soluble multi-branching polysaccharide can be synthesized in high reproducibility in large quantities to enable their use as a functional material on an industrial scale (p. 7, section 0010). Furthermore, unlike natural polysaccharides, the molecular weight and degree of branching can be controlled (p. 7, section 0010).

Although Kakuchi *et al.* teach that the multi-branching polysaccharide is useful as a thickener in a biocompatible gel, the reference does not explicitly teach that the compound can be used as an external preparation for the skin, or as a cosmetic. Furthermore, it is noted that Kakuchi *et al.* do not explicitly teach the limitations of claims 8-11, wherein the multi-branched polysaccharide is present in 0.1 to 80%.

The Wang '319 patent teaches a cosmetic composition comprising a protein/polysaccharide complex. Polysaccharides and proteins are commonly incorporated into cosmetic compositions because they are known to be good humectants, film formers, and function as skin moisturizers (column 1, lines 14-16). Thus, it may be advantageous to make a protein/polysaccharide complex as a means to overcome stability issues faced by proteins and polysaccharides in cosmetic products. Examples of anionic polysaccharides include galactans, galactomannans, glucomannans, and polyuronic acids (column 3, lines 39-44).

As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kakuchi *et al.*, concerning a method for manufacturing multi-branching polysaccharides, with the teachings of the Wang '319 patent, regarding the incorporation of polysaccharides into cosmetic compositions. One

would have been motivated to combine the teachings in order to receive the expected benefit, as suggested by Kakuchi *et al.*, that the water-soluble multi-branching polysaccharide can be synthesized in high reproducibility in large quantities to enable their use as a functional material on an industrial scale (p. 7, section 0010). Furthermore, Kakuchi *et al.* teach that unlike natural polysaccharides, the molecular weight and degree of branching can be controlled (p. 7, section 0010). Hence, one of ordinary skill in the art would reasonably conceive that the synthetic multi-branching polysaccharides would be more useful in a cosmetic preparation than natural polysaccharides as the synthetic polysaccharides are homogeneous in structure.

With regards to the limitation wherein the multi-branched polysaccharide is present in 0.1 to 80%, the Wang '319 patent teaches that a useful range of protein/polysaccharide complex in the composition is in the range of 0.2-30% (column 6, lines 38-41). Hence, it would be *prima facie* obvious for one of ordinary skill to determine a useful range for the polysaccharide in the cosmetic composition. Moreover, it is considered within the capabilities of one of ordinary skill in the art to vary the polysaccharide concentration to determine its most optimal concentration.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Section [0002]

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over journal publication by Kasuya *et al.* (PTO-892, Ref. U) in view of PG Pub No. US 2002/00065328 A1 by Dederen *et al.* (PTO-892, Ref. B).

Kasuya *et al.* teach the chemical synthesis of a branched polysaccharide via cationic ring-opening polymerization and copolymerization of an anhydrodisaccharide monomer. Scheme 2 shows the polymerization of a 1,6-anhydrodisaccharide monomer and the resulting 1,6-linked product which contains a branching glucose residue at the 4-position for each sugar unit in the chain (p. 2132, column 1). Scheme 6 shows the copolymerization of a 1,6-anhydrodisaccharide monomer with a 1,6-anhydromonosaccharide monomer, resulting in a 1,6-linked product that contains a branching glucose residue for every other sugar unit in the chain (p. 2134, column 2). The cationic ring-opening polymerization of anhydro saccharide units are excellent methods for the chemical synthesis of branched polysaccharides with high molecular weight and a well-defined structure (p. 2131, column 1, second paragraph).

Kasuya *et al.* do not teach that the synthetic polymers are useful as an external preparation for the skin or as a cosmetic.

Dederen *et al.* teach a personal care or cosmetic oil in water emulsion that includes an oil emulsifier and a combination of a Xanthan polysaccharide and a polyglucomannan polysaccharide to provide enhanced stability. Personal care products include cosmetic skin creams, lotion and milks (paragraphs 0002 and 0009). Polyglucomannan typically has a random glucose/mannose backbone, typically at a molar ratio of glucose to mannose in the range of about 1:1.5 to about 1:3, with various

acetylated groups (paragraph 0011). The molecular weight of useful polyglucmannans can vary within a typical range of from about 2×10^5 to about 2×10^6 (paragraph 0011). The amount of polysaccharide stabilizer used is from about 0.02% to about 0.5% by weight of the emulsion (paragraph 0018).

It is noted that the references do not explicitly teach the limitations of claim 5, wherein the branching degree of the branched polysaccharide is 0.05 to 1.00. However, Kasuya *et al.* do indicate different methods for modifying the degree of branching based on whether anhydrodisaccharides or anhydromonosaccharides are used in the copolymerization reaction. Therefore, one of ordinary skill in the art would know how to alter the reaction conditions to obtain the desired degree of branching. Moreover, it is considered within the capabilities of one of ordinary skill in the art to vary the ratios of anhydro sugars and other reagents in the reaction, including the type of anhydrosugar, to obtain a polysaccharide with the desired degree of branching, linkage, and sugar units.

As such, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kasuya *et al.*, concerning the chemical synthesis of a branched polysaccharide via cationic ring-opening polymerization and copolymerization of an anhydrodisaccharide monomer, with the teachings of the Dederen '107 patent, regarding a personal care or cosmetic oil in water emulsion that includes an oil emulsifier and a combination of a Xanthan polysaccharide and a polyglucmannan polysaccharide to provide enhanced stability. One would have been motivated to combine the teachings in order to receive the expected benefit, as

suggested by Kasuya *et al.*, that the synthesis of branched polysaccharides by cationic ring-opening polymerization of anhydro saccharides results in products with high molecular weight and a well-defined structure (p. 2131, column 1, second paragraph). Additionally, as the Dederen '107 patent teaches that polyglucomanan is highly heterogeneous, like most natural polysaccharides, one of ordinary skill in the art would reasonably conceive that the cationic ring-opening polymerization of anhydro saccharides that yield branched polysaccharides would be more useful in a cosmetic preparation than natural polysaccharides as the synthetic polysaccharides are homogeneous in structure, thereby providing more reproducible results.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623

/SCARLETT GOON/
Examiner
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